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10/052,486	01/18/2002	Shi-Lung Lin	USP1941A-EI	7295
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Raymond Y. CHAN 108 N. YNEZ AVE. #128			LACOURCIERE, KAREN A	
****	ARK, CA 91754		ART UNIT	PAPER NUMBER
			1635	
,			DATE MAILED: 05/12/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

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Application No. Applicant(s) 10/052,486 LIN. SHI-LUNG Office Action Summary Examiner Art Unit Karen A. Lacourciere 1635 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). **Status** 1) Responsive to communication(s) filed on _____. 2a) This action is **FINAL**. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. **Disposition of Claims** 4) Claim(s) <u>1-116</u> is/are pending in the application. 4a) Of the above claim(s) _____ is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) ____ is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) 1-116 are subject to restriction and/or election requirement. **Application Papers** 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date. ____ Notice of Informal Patent Application (PTO-152) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ___ 6) __ Other: ___

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DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Claims 1-21 and 95-102 drawn to a method of inducing gene silencing effects using cDNA-aRNA hybrids, classified in class 514, subclass 44.
- II. Claims 22-39 and 103-105 drawn to a method for generating cDNA-aRNA hybrids, classified in class 435, subclass 91.1.
- III. Claims 40-58 and 106-111, drawn to a method of RNA polymerase cycling reaction, classified in class 435, subclass 91.2.
- IV. Claims 59-78, 87, 88 and 112-116, drawn to a composition comprising a plurality of cDNA-aRNA hybrid constructs, classified in class 536, subclass 24.5.
- V. Claims 79-81, 83-86, drawn to a therapeutic strategy using a plurality of cDNA-aRNA hybrids classified in class 514, subclass 44.
- VI. Claim 82, drawn to viral infections, classified in class 435, subclass 235.1.
- VII. Claim 89, drawn to information, classified in class 702, subclass 19.
- VIII. Claims 90, 92 and 94, drawn to gene sequences, classified in class 536, subclass 23.1.
- IX. Claims 91, drawn to a polypeptide, classified in class 530, subclass 300.
- X. Claim 93, drawn to a therapeutic drug, classified in class 514, subclass 1.

The inventions are distinct, each from the other because of the following reasons:

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Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different effects. For example, the methods of Group I have the effect of inducing gene silencing, whereas the methods of Group II have the effect of producing a cDNA-aRNA hybrid construct.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different effects. For example, the methods of Group I have the effect of inducing gene silencing, whereas the methods of Group II have the effect of amplifying an RNA sequence.

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the cDNA-aRNA can be used in a method of detection of a gene sequence, which is materially different than the methods of silencing of Group I.

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Inventions I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different effects. For example, the methods of claim 1 have the effect of silencing gene expression, whereas the methods of Group V have the effect of treating a disease.

Inventions I and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a method and a product not capable of use with the method. For example, the viral infections of Group VI are not used in the method of gene silencing of Group I, which uses cDNA-aRNA hybrid constructs.

Inventions I and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a method and a product not capable of use with the method. For example, the information of Group VI is not used in the method of gene silencing of Group I, which uses cDNA-aRNA hybrid constructs.

Inventions I and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the gene sequences can be used in a materially different method than the gene silencing of Group I. For example, the gene sequences of Group VIII can be used in a method of producing a polypeptide.

Inventions I and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a method and a product which is not used in the method wherein the method and product have different functions. For example, the polypeptide of Group IX functions to catalyze a reaction and is not used in the methods of Group I, which function to silence gene expression.

Inventions I and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a method and a product which is not used in the method wherein the method and product have different functions. For example, the therapeutic drug of Group X functions to treat a disease and is not used in the methods of Group I, which function to silence gene expression.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In

the instant case the different inventions are not used together and have different effects. For example, the methods of Group II have the effect of generating cDNA-aRNA hybrids, whereas the methods of Group III have the effect of improved amplification of an RNA sequence.

Inventions II and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made by a materially different method than that of Group II, for example, the product of Group IV can be made by synthesis of each component and ligation to produce the hybrid.

Inventions II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which are not capable of use together and have different effects, for example, the methods of Group II have the effect of generating cDNA-aRNA hybrid constructs, which is different than the methods of Group V, which have the effect of treatment of a disease.

Inventions II and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a composition and a method,

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wherein the composition is not used in the method. For example, the method of generating cDNA-aRNA hybrids of Group II have the effect of producing hybrid constructs and do not utilize the compositions of Group VI, which have the effect of causing a viral infection.

Inventions II and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a composition and a method, wherein the composition is not used in the method. For example, the method of generating cDNA-aRNA hybrids of Group II have the effect of producing hybrid constructs and do not utilize the information of Group VII, which function to provide information.

Inventions II and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions drawn to a composition and a method, wherein the composition is not used in the method. For example, the method of generating cDNA-aRNA hybrids of Group II have the effect of producing hybrid constructs and do not utilize the gene sequences of Group VII, which function to encode a protein.

Inventions II and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions drawn to a composition and a method, wherein the composition is not used in the method. For example, the method of generating cDNA-aRNA hybrids of Group II have the effect of producing hybrid constructs and do not utilize the polypeptides of Group IX, which function to catalyze reactions.

Inventions II and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions drawn to a composition and a method, wherein the composition is not used in the method. For example, the method of generating cDNA-aRNA hybrids of Group II have the effect of producing hybrid constructs and do not utilize the therapeutic drugs of Group X, which function to treat a disease.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a method and a composition that is not used in the method. For example, the RNA polymerase cycling reaction functions to amplify a target gene sequence and does not utilize the cDNA-aRNA hybrids of Group IV, which function to reduce the expression of a gene.

Inventions III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In

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the instant case the different inventions are drawn to materially different methods with different effects. For example, the RNA polymerase cycling reaction has the effect of amplifying a target gene sequence, and is materially different than the therapeutic strategy of Group V which has the effect of providing a strategy for treating a disease.

Inventions III and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a method and a composition that is not used in the method. For example, the RNA polymerase cycling reaction functions to amplify a target gene sequence and does not utilize the viral infections of Group VI, which function to cause a disease.

Inventions III and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a method and a composition that is not used in the method. For example, the RNA polymerase cycling reaction functions to amplify a target gene sequence and does not utilize the information of Group VII, which functions to provide information.

Inventions III and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

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process of using that product (MPEP § 806.05(h)). In the instant case the gene sequence product of Group VIII can be used to express a protein in a method of purification, which is materially different that the method of RNA polymerase cycling of Group III.

Inventions III and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a method and a composition that is not used in the method. For example, the RNA polymerase cycling reaction functions to amplify a target gene sequence and does not utilize the polypeptides of Group IX, which function to catalyze reactions.

Inventions III and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a method and a composition that is not used in the method. For example, the RNA polymerase cycling reaction of Group III functions to amplify a target gene sequence and does not utilize the therapeutic drug of Group X, which functions to treat a disease.

Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

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process of using that product (MPEP § 806.05(h)). In the instant case the cDNA-aRNA hybrid constructs of Group IV can be used in a method of determination of gene function, in a cell in vitro, which is materially different than the therapeutic strategy of Group V.

Inventions IV and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different products with different functions. For example, the cDNA-aRNA hybrid constructs of Group IV function to decrease the expression of a target gene, which is different than the viral infections of Group VI, which function to cause a disease.

Inventions IV and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different products with different functions. For example, the cDNA-aRNA hybrid constructs of Group IV function to decrease the expression of a target gene, which is different than the information of Group VII, which function to inform.

Inventions IV and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In

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the instant case the different inventions are drawn to materially different products with different functions. For example, the cDNA-aRNA hybrid constructs of Group IV function to decrease the expression of a target gene, which is different than the gene sequences of Group VIII, which function to encode a protein.

Inventions IV and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different products with different functions. For example, the cDNA-aRNA hybrid constructs of Group IV function to decrease the expression of a target gene, which is different than the polypeptides of Group IX, which function to catalyze a reaction.

Inventions IV and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different products with different functions. For example, the cDNA-aRNA hybrid constructs of Group IV function to decrease the expression of a target gene, which is different than the therapeutic drugs of Group X, which function to treat a disease.

Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a method and a product which is

not used in the method. For example, the therapeutic strategy of Group V has the function of providing a strategy for treating a disease and does not utilize the viral infections of Group VI, which function to cause a disease.

Inventions V and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a method and a product which is not used in the method. For example, the therapeutic strategy of Group V has the function of providing a strategy for treating a disease and does not utilize the information of Group VII, which functions to inform.

Inventions V and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a method and a product which is not used in the method. For example, the therapeutic strategy of Group V has the function of providing a strategy for treating a disease and does not utilize the gene sequences of Group VIII, which function to encode a polypeptide.

Inventions V and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a method and a product which is not used in the method. For example, the therapeutic strategy of Group V has the

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function of providing a strategy for treating a disease and does not utilize the polypeptides of Group IX, which function to catalyze a reaction.

Inventions V and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the therapeutic drug can be used in a materially different method of using the product, for example, the drug can be used in a method of high through put screening.

Inventions VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different compositions with different functions, for example, the viral infections of Group VI function to cause a disease, which is different than the information of Group VII, which functions to inform.

Inventions VI and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different compositions with different functions, for example, the viral infections of Group VI function to cause a disease, which is different than the gene sequences of Group VIII, which function to encode a protein.

Inventions VI and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different compositions with different functions, for example, the viral infections of Group VI function to cause a disease, which is different than the polypeptides of Group IX, which function to catalyze a reaction.

Inventions VI and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different compositions with different functions, for example, the viral infections of Group VI function to cause a disease, which is different than the therapeutic drugs of Group X, which function to treat a disease.

Inventions VII and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different compositions with different functions, for example, the information of Group VII functions to inform, which is different than the gene sequences of Group VIII, which function to encode proteins.

Inventions VII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different compositions with different functions, for example, the information of Group VII functions to inform, which is different than the polypeptides of Group IX which function to catalyze reactions.

Inventions VII and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different compositions with different functions, for example, the information of Group VII functions to inform, which is different than the therapeutic drugs of Group X, which function to treat a disease.

Inventions VIII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different compositions with different functions. For example, the gene sequences of Group VIII are composed of nucleotides and function to encode polypeptides, whereas the polypeptides of Group IX are composed of amino acids and function to catalyze reactions.

Inventions VIII and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

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operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different compositions with different functions. For example, the gene sequences of Group VIII function to encode polypeptides, whereas the therapeutic drugs of Group X function to treat a disease.

Inventions IX and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different compositions with different functions. For example, the polypeptides of Group IX function to catalyze a reaction, whereas the therapeutic drugs of Group X function to treat a disease.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Lacourciere whose telephone number is (571) 272-0759. The examiner can normally be reached on Monday-Thursday 7:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (571) 272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Lacourciere May 10, 2004

KAREN A. LACOURCIERE, PH.D. PRIMARY EXASTINER

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